

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO
PAR INNOVATION COMPANY, LLC,

Plaintiffs,

v.

LUITPOLD PHARMACEUTICALS, INC.,
DAIICHI SANKYO, INC., and DAIICHI
SANKYO COMPANY, LTD.,

Defendants.

OPINION

Civ. No. 16-02290 (WHW)(CLW)

Walls, Senior District Judge

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively “Par” or “Plaintiffs”) move under Federal Rule of Civil Procedure 60(a), or alternatively Rule 59(e) to amend the Court’s January 17, 2017 Order granting Defendant Luitpold Pharmaceuticals, Inc.’s (“Luitpold”) motion for judgment on the pleadings, ECF No. 106. ECF No. 107. Plaintiffs request that the Court amend its Order to clarify that Counts II and IV of Plaintiff’s Amended Complaint are dismissed *without prejudice*. ECF No. 108 at 3. Defendants Luitpold, Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd. (collectively, “Defendants”) responded by way of a cross-motion for dismissal with prejudice and entry of judgment in favor of Defendants. ECF No. 111. Defendants seek entry of an Order “(1) denying Par’s Motion to Amend Order; (2) dismissing all Counts of the Complaint against Defendants with prejudice; (3) granting judgment in favor of Luitpold on Luitpold’s Counterclaim I against Plaintiffs; (4) dismissing Luitpold’s Counterclaims II and III against Plaintiffs without prejudice;

(5) awarding fees to Defendants and against Plaintiffs in accordance with Defendants’ motion for fees . . . and (6) entering final judgment in favor of Defendants and against Plaintiffs . . .” *Id.* at 1–2. The Court addresses these requests with the exception of Defendants’ fee demand, which will be considered separately in response to Defendants’ motion for fees under 35 U.S.C. § 285. *See* ECF No. 112.

The Court decides this motion without oral argument under Fed. R. Civ. P. 78. Plaintiffs’ motion is granted; Defendants’ motion is granted in part and denied in part.

LEGAL STANDARD AND DISCUSSION

Under Federal Rule of Civil Procedure 60(a), “[t]he court may correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record.” Fed. R. Civ. P. 60(a). *Pfizer, Inc. v. Uprichard*, 422 F.3d 124, 129–30 (3d Cir. 2005). Under Rule 59(e), district courts possess the power to alter or amend a judgment after its entry provided the movant files no later than 28 days after the entry of the judgment. Fed. R. Civ. P. 59(e).

Both Plaintiffs and Defendants seek changes to the Court’s January 17, 2017 Order. ECF Nos. 107, 111. The Parties agree on several of the sought after entreaties. Plaintiffs do not object to Defendants’ request that Luitpold’s Counterclaims II and III be dismissed without prejudice. ECF No. 117 at 9. Additionally, Plaintiff correctly notes that Defendants’ request for judgment on Luitpold’s Counterclaim I is moot because judgment was already granted on this claim. *See* ECF No. 106. The main source of disagreement lies in whether all counts asserted against Defendants in Plaintiffs’ Amended Complaint should be dismissed with prejudice or whether Plaintiffs’ Counts II and IV in the Amended Complaint should be dismissed without prejudice.

NOT FOR PUBLICATION

Counts II and IV of the Amended Complaint sought a declaration under the Declaratory Judgment Act that the future product Luitpold will ultimately market will match Par's formulation and will infringe the asserted patents under 35 U.S.C. § 271(a), (b), (c), and/ or (g). *See* ECF No. 71 ¶¶ 69–72, 77–80. Par argues that Counts II and IV in the Amended Complaint should therefore be dismissed without prejudice because they are directed to future formulations of Luitpold's product, which the Court recognized "are not ripe for adjudication." ECF No. 108 at 2. Consequently, they argue, the Court should dismiss without prejudice because it has "effectively concluded that it lacks subject matter jurisdiction to hear Par's Counts II and IV." *Id.* at 3.

First, Defendants respond that "the effect of a dismissal without prejudice is that Par would be free to file a new complaint alleging identical facts to those pled in Counts II and IV, which the Court has already found are entirely premised on speculation. ECF No. 111-1 at 2. They further argue that dismissal with prejudice is appropriate because the deficiencies in Plaintiffs' Amended Complaint "could not be cured by refileing." *Id.* at 3. Finally, Defendants contend that dismissal with prejudice "will not prejudice Par from filing a new lawsuit if Luitpold actually changes its formulation into an infringing formulation." *Id.* at 4.

Plaintiffs reply that they could face prejudice if the Court does not dismiss without prejudice if a future court incorrectly concludes that the Court's January 17, 2017 Order has preclusive effect. Though both the Court and Defendants acknowledge that Par would have a claim if Luitpold materially changed its ANDA, ECF No. 105 at 14 & n.4, Par maintains that dismissing Counts II and IV without prejudice is necessary to ensure Par can bring a new suit if Defendants modify their ANDA product. ECF No. 117 at 5.

NOT FOR PUBLICATION

The Parties agree that Counts II and IV seek a declaratory judgment based on a speculative product; namely, Luitpold's potential future generic epinephrine product. As the Court explained in its January 17, 2017 Opinion, such speculative claims of infringement are not ripe for adjudication. ECF No. 105 at 15; *see also Step-Saver Data Sys., Inc. v. Wyse Tech.*, 912 F.2d 643, 647 (3d Cir. 1990) ("The discretionary power to determine the rights of parties before injury has actually happened cannot be exercised unless there is a legitimate dispute between the parties."). The Court therefore agrees with Plaintiffs that Counts II and IV must be dismissed without prejudice. *See Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990) (affirming dismissal without prejudice because infringement allegation was not yet ripe); *see also NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 341 (3d Cir. 2001) (explaining a ripeness challenge as a challenge to a case's subject matter jurisdiction).

CONCLUSION

Plaintiffs' motion to amend, ECF No. 107, is granted. Defendants' cross-motion, ECF No. 111, is granted in part and denied in part. Defendants' request for entry of judgment as to its First Counterclaim is moot as judgment was previously entered. An amended order follows.

DATE:

8 March 2017



William H. Walls
Senior United States District Court Judge